IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARINA KEE,	:	CIVIL ACTION
	:	NO. 11-7789
Plaintiff,	:	
	:	
v.	:	
	:	
ZIMMER, INC.,	:	
	:	
Defendant.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. MAY 17, 2012

Defendant prescription medical device manufacturer moved to dismiss Counts I-VII and IX because, inter alia, Pennsylvania law does not impose liability for harm caused by a prescription device manufacturer under theories not based on negligence. For the reasons that follow, the Court will grant the motion and dismiss Counts I-VII and IX.

I. BACKGROUND[1]

On August 26, 2009, Marina Kee ("Plaintiff") complained to Robert E. Booth, Jr., M.D., ("Dr. Booth") of knee pain. Compl. ¶ 23, ECF No. 1. Dr. Booth diagnosed Plaintiff with

[1] For purposes of disposing of the Motion to Dismiss, the Court accepts all well-pleaded factual allegations in the Complaint as true and draws all inferences in the light most favorable to Plaintiff.

advanced degenerative arthritis of both knees and recommended total knee replacement. Id. ¶¶ 24-25. On September 29, 2009, Plaintiff underwent bi-lateral total knee arthroplasties at Bryn Mawr Hospital, where Dr. Booth implanted the Zimmer NexGen, Legacy Posterior Stabilized flex knee system ("LPS System"). Id. ¶ 27. Zimmer, Inc., ("Defendant") designs, manufactures, and distributes the LPS System. Id. ¶¶ 7-10.

In January, 2011, Plaintiff complained of left knee pain; two doctors diagnosed her with apparent loosening of the tibial component implanted by Dr. Booth on September 29, 2009. Id. ¶¶ 28-29. On February 21, 2011, Eric A. Levicoff, M.D., an orthopedic specialist, recommended knee replacement. Id. ¶ 30. On March 18, 2011, Plaintiff underwent the surgery. Id. ¶ 31.

II. PROCEDURAL HISTORY

On August 24, 2011, Plaintiff commenced a civil action in the Court of Common Pleas of Philadelphia County by filing a writ of summons. Notice of Removal ¶ 1, ECF No. 1. On December 5, 2011, Plaintiff filed a Complaint asserting the following nine counts: defective design (Count I); failure to warn (Count II); violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL") (Count III); fraud (Count IV); breach of implied warranty of fitness (Count V); breach of implied warranty of merchantability (Count VI); breach of

express warranty (Count VII); negligent design and manufacture (Count VIII); and punitive damages (Count IX). Compl ¶¶ 32-109.

Defendant removed to the U.S. District Court for the Eastern District of Pennsylvania invoking this Court's diversity jurisdiction.[2] Notice of Removal ¶ 8. On January 27, 2012, Defendant filed a Motion to Dismiss Counts I-VII and IX of the Complaint. Mot. to Dismiss 1, ECF No. 6. Plaintiff responded. Pl.'s Resp. 1, ECF No. 7. And Defendant moved for leave to reply with a proposed reply memorandum attached to the motion. Def.'s Reply 1, ECF No. 8. The Court held a hearing on May 8, 2012, and now decides the motion.

III. LEGAL STANDARD

A party may move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering such a motion, the Court must "accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party." DeBenedictis v. Merrill Lynch & Co., 492 F.3d 209, 215 (3d Cir. 2007) (internal quotation marks removed). To withstand a motion to dismiss, the complaint's "[f]actual allegations must be enough to raise a

[2] Plaintiff is a resident of Pennsylvania. Compl. ¶ 1. Defendant is incorporated in Delaware and maintains a principal place of business in Indiana. Id. ¶ 2.

right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). This "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. Although a plaintiff is entitled to all reasonable inferences from the facts alleged, a plaintiff's legal conclusions are not entitled to deference and the Court is "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986).

The pleadings must contain sufficient factual allegations so as to state a facially plausible claim for relief. See, e.g., Gelman v. State Farm Mut. Auto. Ins. Co., 583 F.3d 187, 190 (3d Cir. 2009). "'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In deciding a Rule 12(b)(6) motion, the Court limits its inquiry to the facts alleged in the complaint and its attachments, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon these documents. See Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994); Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1196 (3d Cir. 1993).

IV. DISCUSSION

Defendant moves to dismiss Counts I-VII and IX. Federal courts sitting in diversity generally apply the substantive law of the forum state. See Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938). Here, the parties do not dispute that Pennsylvania law controls the rule of decision.

A. Pennsylvania Law Bars Strict-Liability and Implied-Warranty Claims Against Prescription Medical Device Manufacturers

Defendant moves to dismiss all non-negligence claims pursuant to comment k to the Restatement (Second) of Torts § 402A (1965). Pennsylvania adopted comment k of § 402A, which imposes strict liability on sellers of unreasonably dangerous products. See Hahn v. Richter, 673 A.2d 888, 889-91 (Pa. 1996). Comment k, however, provides an exception to imposition of strict liability for "unavoidably unsafe products." See Restatement (Second) of Torts § 402A cmt k. In Hahn, the Pennsylvania Supreme Court held that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." Id. at 891; see also Kline v. Pfizer, Inc., No. 08-3238, 2008 WL 478577, at *2-3 (E.D. Pa. Oct. 31, 2008) (dismissing claims based on strict products

liability, breach of express and implied warranties, and fraudulent misrepresentation against drug manufacturer because, under Pennsylvania law, negligence is sole cause of action for failure to warn).

And, although the Pennsylvania Supreme Court has not yet extended Hahn to prescription medical device manufacturers, the Pennsylvania Superior Court has done so. See, e.g., Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (applying comment k to medical devices). Numerous federal district courts, including this Court, have predicted that the Pennsylvania Supreme Court would, if faced with the issue, similarly extend comment k to prescription medical devices. See Horsmon v. Zimmer Holdings, Inc., No. 11-1050, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011) (Bissoon, J.) (predicting that Pennsylvania Supreme Court would apply comment k to prescription medical devices); Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007) (Robreno J.) (same); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 442 (E.D. Pa. 2004) (Kelly, J.) (same); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (Diamond, J.) (same); Murray v. Synthes (U.S.A.), Inc., No. 95-7796, 1999 WL 672937, at *6-8 (E.D. Pa. Aug. 23, 1999) (Hutton, J.) (same); Burton v. Danek Med., Inc., No. 95-5565, 1999 WL 118020, at *7 (E.D. Pa. Mar. 1, 1999) (Kelly, J.) (same); Taylor v. Danek Med., Inc., No. 95-7232,

1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998) (Broderick, J.) (same). Therefore, as a matter of Pennsylvania law, there is no strict liability for harm caused by medical devices.[3]

Plaintiff recognizes state and federal authority holding that, as a matter of Pennsylvania law, actions for harm caused by prescription medical devices must proceed on a theory of negligence. Pl.'s Resp. 4 n.9. Plaintiff argues, however, that the Pennsylvania Supreme Court would not impose a blanket exemption on medical device manufacturers but would instead conduct a "case-by-case, product-by-product analysis" of whether

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[3] For similar reasons, the implied warranties of fitness for a particular purpose and merchantability "are inapplicable to prescription medical devices in Pennsylvania." Soufflas, 474 F. Supp. 2d at 752; see Makripodis v. Merrell-Dow Pharm., Inc., 523 A.2d 374, 377 (Pa. Super. Ct. 1987) ("Thus, we find that the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes,' as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient."); see also Kester v. Zimmer Holdings, Inc., No. 10-523, 2010 WL 2696467, at *11 (W.D. Pa. June 16, 2010) ("As with strict products liability claims for failure-to-warn, Pennsylvania courts have held that the nature of prescription drugs and prescription medical devices precludes claims for breach of implied warranty." (emphasis in original)); Parkinson, 315 F. Supp. 2d at 753 ("As breach of implied warranty claims for prescription drugs are precluded under Pennsylvania law, breach of implied warranty claims for prescription medical devices also are precluded for identical reasons."); Taylor, 1998 WL 962062, at *14 (predicting that Pennsylvania Supreme court would exclude cause of action based on implied warranty of merchantability for prescription medical devices). Therefore, as a matter of Pennsylvania law, there is no liability for breach of implied warranty with respect to prescription medical devices.

the prescription medical device at issue is indeed unavoidably unsafe. Id. at 5. Plaintiff does not cite to authority either from Pennsylvania state cases or federal courts predicting Pennsylvania law for this proposition, nor does she distinguish the state and federal authority to the contrary. Even assuming that Plaintiff's argument that a case-by-case analysis is a "better course of action," this is not the law in Pennsylvania. Id. And a federal court in a diversity action is not free to enforce its policy predilections at the expense of state law. Therefore, the Court will dismiss Counts I and II (strict-liability claims) and Counts V and VI (breach of implied warranties).[4] See Horsmon, 2011 WL 5509420, at *1-3 (dismissing

[4] Defendant moved to dismiss all non-negligence claims under Hahn. The Pennsylvania Supreme Court declared that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." Hahn, 673 A.2d at 891. Defendant reads this provision to mean that all claims against a medical device manufacturer must proceed on a theory of negligence. Although Plaintiff did not raise this argument, Defendant's reliance on Hahn to dismiss all non-negligence claims takes Hahn beyond the scope of its holding. In fact, Hahn dealt with an exception to strict products liability under § 402A. Hahn did not consider other theories of liability, such as fraud and breach of warranty, which Plaintiff alleges here. Therefore, while Plaintiff's claims relating to strict products liability are barred by Pennsylvania's adoption of comment k, the Court must now go on to consider whether Plaintiff successfully states a claim with respect to the remaining non-negligence claims.

strict-liability and breach-of-implied-warranties claims against medical device manufacturer under Pennsylvania law).

B. Plaintiff Failed to Plead Notice for Breach-of-Warranty Claims

Defendant moves to dismiss Plaintiff's breach-of-warranty claims because Plaintiff failed to plead notice pursuant to Pennsylvania law. Where tender is accepted, a buyer must "within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." 13 Pa. Cons. Stat. Ann. § 2607(c)(1) (West 2012). "[T]he purpose of notification under § 2607(c) is to allow the seller an opportunity to resolve the dispute regarding an alleged breach before the buyer initiates a lawsuit." Am. Fed'n of State Cnty. & Mun. Emps. ("AFSCME") v. Ortho-McNeil-Janssen Pharm., Inc., No. 08-5904, 2010 WL 891150, at *6 (E.D. Pa. Mar. 11, 2010). Plaintiff bears the burden to prove compliance with § 2607 before recovering for breach of warranty. See Vanalt Elec. Constr. Inc. v. Selco Mfg. Corp., 233 F. App'x 105, 108-10 (3d Cir. 2007). In context of a motion to dismiss, Plaintiff must "plead, at a minimum, . . . that [she] provided reasonable notification . . . to state a viable claim for recovery . . . or be barred from any remedy." AFSCME, 2010 WL 591150, at *7 (internal quotation marks removed). Here, Plaintiff failed to plead notice.

In response, Plaintiff argues that she is not a "buyer" under § 2607(c)[5] but is, rather, a "third party beneficiary of the relationship which existed between the plaintiff's treating orthopedic surgeon or his practice group and the defendant enjoying standing to advance the instant theory of recovery." Pl.'s Resp. 8 (citing AFSCME, 2010 WL 891150). Plaintiff is confused. In AFSCME, the court held that third-party payers "are in fact considered both 'persons' and 'buyers' under the UCC." AFSCME, 2010 WL 891150, at *7. Thus, Plaintiff is a "buyer" under § 2607(c). Because Plaintiff failed to plead notice with respect to her claims for breach of implied and express warranties, the Court will dismiss Counts V, VI, and VII. See id.

C. The Learned Intermediary Doctrine Bars a Claim Under the Pennsylvania Unfair Trade Practices and Consumer Protection Law

Defendant moves to dismiss Plaintiff's claim alleging a violation of the UTPCPL because the learned intermediary doctrine precludes Plaintiff from establishing the elements of reliance and causation necessary for such a claim. The UTPCPL prohibits "unfair methods of competition" and "unfair or deceptive acts or practices." 73 Pa. Cons. Stat. Ann. § 201-3

[5] A "buyer" is "[a] person who buys or contracts to buy goods." 13 Pa. Cons. Stat. Ann. § 2103(a) (West 2012).

(West 2012). The UTPCPL provides various definitions of unfair methods of competition, including one catch-all provision. See id. § 201-4. "The statute creates a private right of action in persons upon whom unfair methods of competition and unfair or deceptive acts or practices are employed and who, as a result, sustain an ascertainable loss." Hunt v. U.S. Tobacco Co., 538 F.3d 217, 221 (3d Cir. 2008) (quotation and editorial marks removed).

Under Pennsylvania law, a consumer does not have a cause of action under the UTPCPL against the manufacturer of prescription drugs because prescription drug manufacturers do not have a duty to disclose information directly to consumers. Permitting a cause of action under UTPCPL would result in effectively making prescription drug manufacturers absolute guarantors of any anticipated effects of the drug. See Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 384 (D.N.J. 2004) (citing Albertson v. Wyeth Inc., No. 2944 Aug. Term 2002, 0007, 2003 WL 21544488, at *11-12 (Pa. Ct. Com. Pl. July 8, 2003); Luke v. Am. Home Prods. Corp., No. 1998-C-01977, 1998 WL 1781624, at *8 (Pa. Ct. Com. Pl. Nov. 18, 1998)). This is so because a claim under the UTPCPL requires proof of causation and reliance, and the "learned intermediary doctrine breaks the chain in terms of reliance, [because] the patient cannot obtain prescription drugs without the physician no matter what [the patient] believe[s]

about them." Id. In other words, "a private right of action under the UTPCPL requires proof of justifiable reliance and causation, and such requirements cannot be present when the defendant is a pharmaceutical company that did not sell its product directly to the patient." Kester, 2010 WL 2696467, at *14. The same reasoning extends to manufacturers of prescription medical devices. See id. at *14-15 (dismissing UTPCPL claim against prescription medical device manufacturer). Therefore, the learned intermediary doctrine breaks the chain of causation and reliance with respect to Plaintiff's UTPCPL claim. See id.

In response, Plaintiff argues that she is relying on the "catch all" provision of the UTPCPL.[6] Plaintiff recognizes that under Third Circuit precedent, to state a claim under the UTPCPL, including the catch-all provision, she must plead justifiable reliance. See Hunt, 538 F.3d at 222-23, 227 (holding that Pennsylvania Supreme Court would require plaintiff to prove justifiable reliance in alleging deceptive conduct under UTPCPL's catch-all provision). But Plaintiff now argues that

[6] In fact, in the Complaint, Plaintiff relies on various definitions of deceptive practices under the UTPCPL. UTPCPL's so-called "catch-all" provision defines "unfair methods of competition" and "unfair or deceptive acts or practices" to mean "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 Pa. Cons. Stat. Ann. § 202-2(4)(xxi). In the Complaint, Plaintiff relies on various UTPCPL definitions of unfair or deceptive practices. See Compl. ¶ 60 (citing 73 Pa. Cons. Stat. Ann. § 201-2(4)(v), (vii), (xxi)).

some courts have imposed, under the catch-all provision, "a less rigorous level of proof that falls short of actual fraud and have eliminated the requirement to plead reliance and causation in a strict sense." Pl.'s Resp. 10. The Third Circuit's decision in Hunt interpreting this area of Pennsylvania law is clear. And Plaintiff fails to point to dispositive authority in disagreement with Hunt. Under Hunt, the UTPCPL requires justifiable reliance, not a lesser causation standard. Therefore, the Court will dismiss Count III.

D. Plaintiff Fails to Plead Fraud and UTPCPL Claims with Requisite Particularity

Defendant moves to dismiss Plaintiff's fraud and UTPCPL claims under Rule 9(b). Under Pennsylvania law, "to establish common law fraud, a plaintiff must prove: (1) misrepresentation of a material fact; (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded upon the misrepresentation; and (5) damage to the party defrauded as a proximate result." Colaizzi v. Beck, 895 A.2d 36, 39 (Pa. Super. Ct. 2006). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Rule 9(b) requires the following:

> [A] plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged. To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.

Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007) (internal quotation and editorial marks and citation removed).

Plaintiff fails to allege a claim of fraud with sufficient particularity. Plaintiff generally alleges Defendant knew or should have known of the LPS System's "defective nature" and "risk of failure and complication associated with the product," but failed to disclose those facts to the public, its sales representatives, its distributors and customers, doctors, and Plaintiff. Compl. ¶¶ 65-67. Furthermore, Plaintiff alleges Defendant "[m]isled [its] customer base and the consuming public" by failing to notify them of an increased risk of aseptic loosening and total arthroplasty failure after it learned of the malfunction. Id. ¶ 68. Instead, Defendant concealed these facts. Id. ¶ 69. And Plaintiff's allegations under the UTPCPL are similarly vague. There, Plaintiff alleges Defendant mislead and deceived consumers by failing to disclose that the LPS System did not perform safely its represented functions. Id. ¶ 60.

Plaintiff fails to allege facts supporting the nature of her reliance or specific representations Defendant made relating to the reliance. Plaintiff fails to allege facts indicating the date, time, and place of the alleged fraud, or, alternatively, inject any precision or measure of substantiation into her fraud allegations that would "place the defendant on notice of the precise misconduct with which it is charged." Frederico, 507 F.3d at 200; see also Kester, 2010 WL 2696467, at *13-14 (dismissing fraud-based claim against prescription medical device manufacturer when plaintiff failed to allege claim with sufficient particularity under Rule 9(b)). Therefore, the Court will dismiss Counts III and IV.

E. Plaintiff Fails to Allege Outrageous Conduct for Punitive Damages

Defendant moves to dismiss Count IX for punitive damages because Plaintiff failed to allege conduct necessary to support an award of punitive damages. First, under Pennsylvania law, there is no independent cause of action for punitive damages; instead, Plaintiff may include a demand for punitive damages within her demand for relief, not as a separate claim.

Furthermore, under Pennsylvania law, punitive damages are an "extreme remedy available in only the most exceptional matters." Phillips v. Cricket Lighters, 883 A.2d 439, 445 (Pa. 2005) (internal quotation marks removed). Punitive damages are

not awarded to compensate the plaintiff but are intended to punish the defendant for egregious behavior and are only available "when the plaintiff has established that the defendant has acted in an outrageous fashion due to either the defendant's evil motive or his reckless indifference to the rights of others." Id. at 445 (internal quotation marks removed). A showing of mere negligence or even gross negligence is insufficient for an award of punitive damages. Id. at 445-46 Rather, a plaintiff must show "the defendant's acts amounted to intentional, willful, wanton or reckless conduct." Id. at 446 (internal quotation marks removed).

Plaintiff does not allege facts that, if proven, show Defendant acted in an outrageous fashion and with a willful disregard of Plaintiff's rights. Plaintiff alleges harm from the malfunction of a prescription medical device and fails to muster any facts indicating that Defendant acted with reckless indifference to Plaintiff's rights. Therefore, the Court will dismiss Count IX. See Saltzman v. TD Bank, No. 10-3265, 2011 WL 1193112, at *8-9 (E.D. Pa. Mar. 29, 2011) (dismissing claim for punitive damages when plaintiff failed to allege outrageous conduct).

V. CONCLUSION

For the foregoing reasons, the Court will grant the motion to dismiss and dismiss Counts I-VII and IX. The case shall proceed against Defendant on Count VIII (negligence) only. An appropriate order will follow.